UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

IN RE: FOSAMAX PRODUCTS LIABILITY LITIGATION	1:06-MD-1789-JFK **OPINION & ORDER**
This Document Relates to:	
Shirley Boles v. Merck & Co., Inc.	
Case No. 1:06-cv-09455-JFK	

APPEARANCES:

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JOHN F. KEENAN, United States District Judge[1]:

Before the Court is Defendant Merck & Co., Inc.'s ("Merck") motion for summary judgment against Plaintiff Shirley Boles ("Boles"). This case is the first of three bellwether trials in a multi-district products liability litigation concerning the osteoporosis drug Fosamax. For the reasons set forth below, the motion is granted in part and denied in part.

I. BACKGROUND

The following facts are taken from the parties' Local Rule 56.1 Statements, the affidavits submitted in connection with the instant motion, and the exhibits attached thereto. Unless otherwise noted, the facts are undisputed.

A. Fosamax[2]

Fosamax is an oral bisphosphonate manufactured by Defendant Merck for the treatment of osteoporosis. The Food and Drug Administration ("FDA") approved this use of Fosamax on September 29, 1995. On April 25, 1997, the FDA approved a labeling indication for Fosamax's use for the prevention of osteoporosis.

[1] To the extent any sealed material is discussed in this opinion, the information is hereby unsealed in light of the strong presumption of public access.

[2] The Court discusses Fosamax's history and characteristics only to the extent that they are relevant to the instant motion. For further information on the drug, see the Court's ruling on the parties' Daubert motions, In re Fosamax Prods. Liab. Litig., No. 06-cv-09455-JFK (July 27, 2009).

The parties dispute when the first report linking bisphosphonate use with development of osteonecrosis of the jaw ("ONJ") was published in the medical literature. Plaintiff points to a textbook by Dr. Robert Marx, a professor of surgery at the University of Miami School of Medicine, which was apparently published in November 2002.[3] The textbook reads, in relevant part,

> The most common bisphosphonates used for osteoporosis, such as alendronate [Fosamax] . . . , are without serious bone necrosis complications when used according to their recommended dosages. However, pamidronate (Aredia, Novartis), used to treat hypercalcemia related to malignancies in the dosage range of one 60- to 90-mg dose intravenously every 1 week to 1 month, produces a significant incidence of exposed nonvital bone in the mandible and/or maxilla.

(Def.'s Ex. 4.) Merck claims that the earliest report was actually a September 2003 letter to the editor, also written by Dr. Marx. The letter was published in the Journal of the Oral and Maxillofacial Surgery and concerned the occurrence of ONJ in patients who took intravenous – as opposed to oral – bisphosphonates. It was not until the spring of 2004 that a published scientific article linked oral bisphosphonate use to the development of ONJ.[4]

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[3] Both parties refer to the textbook as being published in November 2002 even though there is no mention of this date in the book's publication information.

[4] Plaintiff claims that Dr. Alastair Goss reported an even earlier case of Fosamax-induced ONJ in October 2003. None of

In July 2005, Merck made the following FDA-approved addition to Fosamax's label:

> Osteonecrosis of the jaw, generally associated with tooth extraction and/or local infection, often with delayed healing, has been reported in patients taking bisphosphonates. Most reported cases of bisphosphonate-associated osteonecrosis have been in cancer patients treated with intravenous bisphosphonates, but some have occurred in patients with postmenopausal osteoporosis.

(Def.'s Ex. 9 at 13.)

B. Shirley Boles

Plaintiff Shirley Boles is a 71-year-old Florida resident who alleges that she developed ONJ as a result of taking Fosamax. In early July 1997, Dr. James Mills, a board-certified obstetrician and gynecologist, found that Boles suffered from osteoporosis in her hip and osteopenia – lower than normal bone density that is not low enough to be classified as osteoporosis – in her spine.[5] (Def.'s Ex. 10 at 52:11-16.) He prescribed Fosamax for Boles on July 10, 1997. Boles continued to take the

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the exhibits Plaintiff cites actually supports this proposition, however. Plaintiff does not rely on Dr. Goss's report in its arguments, making this dispute immaterial.

[5] Boles's hip T-score was a standard deviation of -2.1, which, according to the National Osteoporosis Foundation Guidelines at the time, was consistent with osteoporosis. (Pl.'s Ex. 14 ¶ 11.) The 2001 amendments to those guidelines classify this T-score as consistent with osteopenia, however. (Id.) While Boles's T-score is relevant to the Court's later analysis, the precise boundary between osteoporosis and osteopenia is not.

drug, with occasional gaps in usage, up through at least February 2006 and possibly as late as October 2006.

On June 13, 2002, a few days after Boles complained to her dentist that she had a loose tooth, two of Boles's teeth were extracted. An infection developed on the left side of Boles's mandible near the site of the extraction. On August 16, 2002, Dr. Charles Elwell, an oral surgeon, performed a debridement of the infected site and curettage of necrotic bone from the area of extraction. In May 2003, Boles complained of swelling under her chin and then, that summer, developed a draining fistula.

According to Dr. Elwell – who has treated Boles's related, ongoing infections since the summer of 2002 – his last evaluation of Boles in December 2007 revealed that she still had an infection. Around that time, he concluded that Boles's "bony changes" and "lack of bone healing" were correlated to the "use of bisphosphonate therapy over a long-term period." (Pl.'s Ex. 12 at 104:12-18.) Dr. Patrick Anastasio, an infectious disease specialist who examined Plaintiff a month earlier in November 2007, reached the same conclusion independently. (Id. at 104:25-105:6.)

Dr. John Hellstein, a clinical professor at the University of Iowa College of Dentistry who specializes in oral and maxillofacial pathology, is Boles's expert on the alleged causal link between her bisphosphonate use and her ONJ. After

examining Boles and her medical records in January 2009, Dr. Hellstein diagnosed her, "to a level of medical certainty," as having "Stage 3 Bisphosphonate Osteonecrosis."[6] (Pl.'s Ex. 6 App. B.) Under questioning from Merck at his March 25, 2009, deposition, Dr. Hellstein admitted that Plaintiff's symptoms in 2003 could be explained by other possible causes, such as denture irritation or an infection.

Plaintiff has also identified a regulatory expert, Dr. Susan Parisian, a former officer of the FDA, who has opined on when Merck should have warned about the risks posed by Fosamax.[7] The parties strongly dispute Dr. Parisian's true position on when Merck should have made such a warning. Specifically, Merck maintains that Dr. Parisian does not believe Merck had a duty to warn prior to October 2003, while Plaintiff claims Dr. Parisian believes Merck's duty to warn may have existed as early as the mid-1990s. In light of the importance of Dr. Parisian's expert

[6] Dr. Hellstein defined bisphosphonate osteonecrosis as follows: "1. The patient is or has been treated with a bisphosphonate. 2. Exposed bone has been present in the maxillofacial region for more than eight weeks; and 3. There is no history of radiation therapy to the jaws." (Pl.'s Ex. 6 App. B.) He defined stage 3 bisphosphonate osteonecrosis as "[e]xposed/necrotic bone in patients with pain, infection, and one or more of the following: pathologic fracture, extra-oral fistula, or osteolysis extending to the inferior border." (Id.)

[7] The Court does not discuss the testimony of Plaintiff's other regulatory expert, Dr. Curt Furberg, because Plaintiff does not rely on this testimony in opposing Merck's motion for summary judgment.

opinion and the contrary interpretations thereof, the Court reproduces the relevant testimony in full.

At her deposition, Dr. Parisian offered the following testimony relevant to Merck's duty to warn:

> Q. Can you identify for me any label for Fosamax – and I'm talking about an FDA-approved label, because all of the labels that accompany a marketed drug have in fact been FDA approved, have they not?
>
> A. Yes.
>
> Q. Can you identify for me any label that you consider to be inadequate to advise physicians of the risks and benefits of Fosamax?
>
> A. Well, in terms of when should they have – if we're talking about osteonecrosis, for example, when was the company aware of osteonecrosis of the jaw, and you could take October of 2003, they were aware and they put that they knew that they were receiving reports, it was in the literature. So at that particular time they were aware of ONJ, so they could have updated their labeling to have included information about that. They didn't. So it would be that if you're thinking about when were they aware of ONJ and where does it not appear in the labeling, it does not appear in the labeling at that point in time.
>
> Q. That's not really my question, Doctor. Here's my question: I have read through your report, and it's a lengthy report. And I do not see in that report any statement that says: I believe that the labeling that accompanied Fosamax was inadequate to advise physicians of the risks associated with the drug at any particular time.
>
> [PLAINTIFF'S COUNSEL]: Object to the –
>
> THE WITNESS: Okay.
>
> [DEFENSE COUNSEL]: The question – the document speaks for itself. My question very simply is: Is there a time or are there labels that you believe are inadequate? And if so, can you identify them for me first. So I know what time – if we're talking about 2003 and everything

before 2003 is fine, I just need to know that, and we can go from there.

A. All right. Well, I used the 2003 [sic]. But if you take, for example, there are reports of exostosis going back in the '90s, which are discussed in here, none of that type of a risk appears in the literature – in the labeling. But I use the 2003 as when we all – the company has agreed that they were aware of ONJ in October 2003, and they didn't change the label.

In here, I do discuss the labeling negotiation that occurred in 2005. And that's – I was trying to go to that.

[DEFENSE COUNSEL]: Let me see if I – I'm going to move to strike the comments as non-responsive to the last answer.

[BY DEFENSE COUNSEL]: And let me ask this question, Doctor: Do you have an opinion as you sit here today and one which you intend to offer as to when osteonecrosis of the jaw should have been incorporated in the Fosamax label?

A. I did. I said October 2003.

Q. All right. Now, as of October 2003, you base that upon the letter to the editor that Marx published showing osteonecrosis of the jaw in bisphosphonate users, correct?

[PLAINTIFF'S COUNSEL]: Objection.

THE WITNESS: That would be one of the things. But I believe also I'm looking at the adverse event reports that they had had for exostosis since 1996.

[DEFENSE COUNSEL]: Let me separate out the adverse event reports for a second and let me ask you about the Marx report. Okay?

A. All right. You want to ask me about the Marx report.

Q. When the Marx report was published in 2003, were there any oral bisphosphonate osteonecrosis cases reported?

A. In terms of the medical literature?

Q. In terms of the letter to the editor in 2003.

A. Okay. That's what I'm saying. In terms of label, what could be on the label, the exostosis – the ONJ term –

[PLAINTIFF'S COUNSEL]: Let her finish.

> [THE WITNESS]: The ONJ term didn't exist before that. So it would have been under the category of exostosis, which was occurring in the report since 1996, I believe it has been in there.
>
> [DEFENSE COUNSEL]: I move to strike as non-responsive.
>
> . . . .
>
> [DEFENSE COUNSEL]: Is it your – do I understand correctly it to be your testimony that as of October 2003, the Fosamax label should have included a reference to osteonecrosis of the jaw?
>
> [PLAINTIFF'S COUNSEL]: Asked and answered.
>
> THE WITNESS: Yes.
>
> [DEFENSE COUNSEL]: And that is based upon what?
>
> A. If you go to paragraph 215 [of my expert report], in their first – Merck is representing to the FDA that its first report of ONJ was October 2003. So that's the number that Merck has gone forth and said that we knew – we gave our first report of ONJ to the FDA on October 2003. Actually, their adverse event reports are before that. But the one that Merck has said over and over is that it was October 2003.

(Pl.'s Ex. 3 at 147:6-149:23.) The paragraph that Dr. Parisian referenced from her expert report reads as follows:

> Merck, as a manufacture[r] of the aminobisphosphonate alendronate, is responsible for monitoring the medical literature about the safety of its product and should have been aware of the reports of [ONJ] by at least 2003. Merck misrepresented to the public, health care providers, and FDA that its first report of ONJ was October 2003. An examination of Fosamax adverse events in FDA's database using reaction terms selected by Merck for coding ONJ reports reveals that there are ONJ reports occurring as far back as the mid-1990's. If Merck had fulfilled its obligations and requirements as a [new drug application] sponsor for Fosamax, and had adequate pharmacovigilance and monitoring methods in place for Fosamax safety, it should have identified reports of ONJ beginning in at

> least the mid-1990's. This was years before the case reports of ONJ by Dr. Marx and Dr. Ruggerio that appeared in the peer-reviewed literature.

(Def.'s Ex. 7 ¶ 215.)

On July 10, 2009, Dr. Parisian testified at a Daubert hearing before the Court and offered additional testimony relevant to the question of when she believes Merck had a duty to warn about Fosamax's risks. On direct, she testified in relevant part as follows:

> Q. Do you have an opinion, Dr. Parisian, with regard to the accuracy of the Fosamax labels that you have reviewed?
>
> . . . .
>
> A. . . . . Where I begin to have problems with the label is when the company, looking – looking at the company documents, not the FDA documents, there begins to be reports that are not present in the label to provide the physician with some of the risk information.
>
> THE COURT: Are you saying that's 1998?
>
> THE WITNESS: 1998, yes, sir.
>
> THE COURT: All right. Go ahead.
>
> A. And in 1999, the company – from the documents I've reviewed in the company, the documents show that the company was getting reports of what they call exostosis.
>
> Q. What is that?
>
> A. It would be abnormal bone appearing in the mouth. And those were not in the label. They were unlisted. And they would have required a manufacturer for pharmacovigilance to have investigated that and to at least put that information in the adverse events, in the adverse reaction, post marketing. And so that was not there in 1999.
>
> . . . .
>
> Q. If I heard you right, about a minute and a half ago, you said that with the 1999, 1999, the day Merck should have been aware of adverse events, that that should have been included in

> their labeling. Is that right? Is that what you just said?
>
> THE WITNESS: Yes, sir, but I said it was adverse reactions.

(Daubert Hr'g Tr. 190:22-193:9.) Dr. Parisian went on to explain the significance of the reports of exostosis:

> THE WITNESS: The term I used was exostosis. Exostosis can be a red flag that you actually may have symptoms that would later be called ONJ. ONJ –
>
> . . . .
>
> THE WITNESS: . . . . Because if you look at – there's a report that Merck did for a database, their database mining report that I discuss in there, and they talk about exostosis. And they have exostosis reports in their database that go back to 1997. So if you took – and 1996. And so if you go and say that exostosis could be a symptom for ONJ, because the term didn't exist until 2003, those would have been things that they needed to look at, because they were handing the report about exostosis in 1997, 1999, and the reports of osteonecrosis of the jaw didn't occur until 2003.

(Id. at 193:22-194:19.)

The Court sought to clarify Dr. Parisian's position further:

> THE COURT: My question is when should they have made the labeling change?
>
> THE WITNESS: 1999 was when the labeling change could have begun.
>
> THE COURT: That's when it should have or could have?
>
> THE WITNESS: It actually could have begun.
>
> THE COURT: When should it have, according to you?
>
> THE WITNESS: It should have begun definitely in 2003 with osteonecrosis of the jaw.
>
> THE COURT: All right. Go ahead.

> THE WITNESS: Which is what I say, but in terms of their investigation, they could have begun in the mid 1990s looking at those exostosis reports.

(Id. at 194:25-195:12.)

The following exchange then took place on cross-examination:

> Q. Dr. Parisian, when I took your deposition in March of this year we asked you specifically when the information about osteonecrosis of the jaw should have been included in the label according to your opinion, did we not?
>
> A. Yes, ma'am, and you asked me specifically about osteonecrosis of the jaw.
>
> Q. And at that point in time you made it very clear on numerous occasions that you had no basis for saying that it should have been included in the label before October of 2003, is that correct?
>
> A. Correct. Because the term didn't exist before 2003.

(Id. at 212:7-17.)

C. Procedural History

On September 1, 2006, Boles filed suit against Merck seeking compensatory and punitive damages based upon claims of negligence, strict liability, breach of express and implied warranties, and fraudulent misrepresentation and concealment. Plaintiff has since withdrawn her express and implied warranty claims.

On May 8, 2009, Merck moved for summary judgment. A month later, on June 6, 2009, Plaintiff produced a declaration from

Dr. Mills apparently in response to Merck's argument that the record was devoid of evidence that Dr. Mills would not have prescribed Fosamax for Boles had he known it could cause ONJ. In the declaration, Dr. Mills stated that, had Merck revealed that Fosamax has no fracture reduction efficacy for patients with a T-score of better than -2.5 standard deviations, Dr. Mills would not have prescribed the drug to Boles (at various times, she has had T-scores of -2.1 and -2.2 – better scores). (Pl.'s Ex. 14 ¶ 11.) Dr. Mills further declared, in relevant part,

> . . . Shirley Boles was on conjugated estrogen treatment at the same time I had her on Fosamax. In the current label for Fosamax, there is information about the combined pharmacological activity of conjugated estrogen treatment and Fosamax on bone turnover, based upon bone biopsy data. There was no precaution or warning that suppressing bone turnover by 94% or 98% could have clinically significant adverse event outcomes. The sales representatives with whom I met merely indicated that this proved the efficacy of the Fosamax treatment. Had I known that the suppression of bone turnover to such an extent could have clinically significant adverse event outcomes, I likely would not have put her on the combined treatment of conjugated estrogen and Fosamax, particularly given her relatively benign T-score. Again, had her T-score worsened to -2.5 standard deviations or worse, I would have advised Shirley Boles about the potential for an adverse outcome from oversuppression of bone turnover, and let her decide whether she was willing to accept the risk, and in no event would I have let Mrs. Boles stay on Fosamax for longer than four years, given the limited period of fracture reduction efficacy.

(Id. ¶ 13.)

For reasons that will be addressed, the Court permitted Merck to redepose Dr. Mills regarding this declaration. Merck did so on July 22, 2009. The parties then submitted supplemental briefs for this motion.

II. DISCUSSION

Merck asks the Court to grant summary judgment based on the following arguments:

(1) Plaintiff's strict liability and negligence claims fail since Merck had no duty to warn at the time of Plaintiff's injury;

(2) Plaintiff cannot show causation;

(3) Plaintiff cannot establish a nexus between her injury and any fraud sufficient to support her fraudulent misrepresentation and fraudulent concealment claim.

(4) Plaintiff's request for punitive damages does not meet the applicable standard.

A. Standard of Review

Summary judgment is appropriate where "the pleadings, the discovery and disclosure materials on file, and any affidavits show that there is no genuine issue as to any material fact and that the movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(c). An issue is genuine "if the evidence is

such that a reasonable jury could return a verdict for the nonmoving party." Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 248 (1986). The moving party bears the burden of demonstrating that summary judgment is appropriate. Celotex Corp. v. Catrett, 477 U.S. 317, 323 (1986). Where the moving party meets that burden, the opposing party must come forward with specific evidence demonstrating the existence of a genuine dispute of material fact. Anderson, 477 U.S. at 249.

In determining whether there is a genuine issue as to any material fact, "[t]he evidence of the nonmovant is to be believed, and all justifiable inferences are to be drawn in his favor." Id. at 255. Where it is clear that no rational finder of fact "could find in favor of the nonmoving party because the evidence to support its case is so slight" summary judgment should be granted. Gallo v. Prudential Residential Servs., Ltd., 22 F.3d 1219, 1224 (2d Cir. 1994).

B. Duty to Warn

Plaintiff's negligence and strict liability claims are both predicated, in part,[8] on Merck's alleged failure to provide a warning that Fosamax can lead to ONJ. Under Florida law,[9]

[8] Plaintiff's complaint sets forth other bases for finding that Defendant was negligent or strictly liable; for example, it alleges that Fosamax is an unreasonably dangerous product in that its risks exceeded its benefits (Compl. ¶ 54.) Merck's motion for summary judgment does not address these other bases.

[9] The parties agree that Florida law governs.

manufacturers of drugs have a duty to provide adequate warnings of dangerous side effects to the prescribing physicians. Buckner v. Allergan Pharms., 400 So. 2d 820, 822 (Fla. Dist. Ct. App. 1981); Upjohn Co. v. MacMurdo, 562 So. 2d 680, 683 (Fla. 1990). To maintain a negligent failure to warn claim, a plaintiff must "prove that a manufacturer or distributor did not warn of a particular risk for reasons which fell below the acceptable standard of care, i.e., what a reasonably prudent manufacturer would have known and warned about." Ferayorni v. Hyundai Motor Co., 711 So. 2d 1167, 1172 (Fla. Dist. Ct. App. 1998) (internal quotation marks omitted). "To establish strict liability for failure to warn, plaintiff must prove that defendant . . . did not adequately warn of a particular risk that was known or knowable in light of the generally recognized and prevailing best scientific and medical knowledge available at the time of the manufacture and distribution." Pinchinat v. Graco Children's Products, Inc., 390 F. Supp. 2d 1141, 1146 (M.D. Fla. 2005) (citing Ferayorni, 711 So. 2d at 1172). Under both standards, the adequacy of the warning is assessed "at the time of injury and at the time in which the product left the manufacturer's control." Colville v. Pharmacia & Upjohn Co., 565 F. Supp. 2d 1314, 1320 (N.D. Fla. 2008) (citing Rodriguez v. Nat'l Detroit, Inc., 857 So. 2d 199, 201 (Fla. Dist. Ct. App. 2003)). "[T]he adequacy or inadequacy of the warning to inform a physician

must, except in the more obvious situations, be proved by expert testimony," MacMurdo, 562 So. 2d at 683, and is "usually a jury question," Felix v. Hoffmann-LaRoche, Inc., 540 So. 2d 102, 105 (Fla. 1989).

Merck argues that it is not liable to Plaintiff under either failure to warn theory unless it had a duty to provide a warning before Plaintiff developed ONJ. See Colville, 565 F. Supp. 2d at 1320. According to Merck, Dr. Parisian, Plaintiff's regulatory expert, opined that the earliest date Merck had a duty to provide a warning was October 2003. Merck claims Dr. Hellstein, Plaintiff's causation expert, testified that Boles had ONJ by August 2002, more than a year earlier. Thus, Merck submits that its duty to warn arose long after Plaintiff suffered her injuries.

1. Timing of the Duty to Warn

Merck misconstrues Dr. Parisian's expert opinion. A full reading of Dr. Parisian's expert report, her testimony at her deposition, and her testimony at the Daubert hearing reveals that she believes Merck's duty to warn was clear by October 2003 and may have existed as early as the mid- to late-1990s. Although Dr. Parisian repeatedly discussed October 2003 as a time by when Merck should have provided a warning, she clarified that this was the latest – not earliest – possible date that Merck's duty to warn arose. For example, at the Daubert

hearing, she testified that Merck "definitely" should have provided a warning by October 2003, but noted that it had sufficient information to provide a warning well before then. (Daubert Hr'g Tr. 195:7-12.) That information came in the form of adverse event reports of exostosis in Fosamax users from the mid- to late-1990s. As Dr. Parisian explained, reports of exostosis are significant because they may represent cases of what would later be known as ONJ, a term not used before 2003. In fact, Dr. Michael Goldberg, Merck's former director of clinical risk management and safety, conceded that at least one of the reports of exostosis cited by Dr. Parisian could have been a case of ONJ. (Pl.'s Ex. 9 at 445:5-446:12.) All of this explains why, in response to the Court's questioning, Dr. Parisian stated that, by 1999, Merck's label should have reflected these reports of exostosis. (Daubert Hr'g Tr. 193:3-9.) Confronted with all of this evidence, a jury could reasonably find that Merck's duty to warn arose before October 2003 and possibly as early as the mid- to late-1990s.

2. Timing of Plaintiff's Injury

Merck also misreads Dr. Hellstein's testimony as stating that Boles developed ONJ in August 2002. Although he did testify that Boles's symptoms in August 2002 were consistent with nascent ONJ, he gave no firm diagnosis. In fact, he later testified that, as of April 2003, Boles's symptoms were "most

likely a denture irritation" rather than ONJ. (Pl.'s Ex. 5 at 255:22-23). Then, regarding Boles's September 2003 symptoms, Dr. Hellstein could only say, "I think she could meet stage zero [bisphosphonate-related] ONJ by . . . the [American Association of Oral and Maxillofacial Surgeons] definition." (Pl.'s Ex. 5 at 292:19-23 (emphasis added).) (Stage zero is the earliest stage of the disorder.) It was not until the Court's Daubert hearing that Dr. Hellstein attempted to set a somewhat firm date for the onset of Boles's ONJ: "It would be some time in the area of 2005." (Daubert Hr'g Tr. 338:24.) Dr. Hellstein's testimony, then, does not support Merck's interpretation.

Nonetheless, the Court finds that Plaintiff has conceded, by means of judicial admissions, that she had ONJ by no later than September 2003. The Court reaches this conclusion based on statements in Plaintiff's brief on the instant motion. First, in rebutting Merck's challenge to the reliability of Dr. Hellstein's expert opinion on specific causation, Plaintiff stated, "Boles has had exposed bone in her jaw for several years. Despite the administration of long-term antibiotics and adequate debridement, the zone of dead bone that appeared in Plaintiff's mouth in the summer of 2002 had not healed by August 2003, and has remained stable since." (Pl.'s Mem. in Opp'n 15 (citation omitted).) Then, in support of her request for punitive damages, Plaintiff stated that Merck denied having

knowledge of the risk of ONJ "until it was published in autumn 2003 – too late to save Plaintiff's jaw." (Id. at 20.) Plaintiff refers here to Dr. Marx's September 2003 letter to the editor. The Court construes these statements as judicial admissions that Plaintiff had ONJ by no later than September 2003. See Purgess v. Sharrock, 33 F.3d 134, 144 (2d Cir. 1994) ("A court can appropriately treat statements in briefs as binding judicial admissions of fact."); see also Guadagno v. Wallack Ader Levithan Assoc., 950 F. Supp. 1258, 1261 (S.D.N.Y. 1997) ("[Judicial admissions are] not evidence at all but rather have the effect of withdrawing a fact from contention." (quoting Keller v. United States, 58 F.3d 1194, 1199 n.8 (7th Cir. 1995))).

The Court recognizes that Plaintiff took a different stance in her discussion of the failure to warn claims. There, she claimed that Dr. Hellstein "was not staking out an affirmative position that [Boles] had ONJ by September 2003." (Pl.'s Mem. in Opp'n 12.) She suggested that his somewhat ambiguous testimony created an "issue[] of fact as to when [Boles] developed [ONJ]." (Id.) These statements do not change the Court's analysis. Plaintiff cannot allege one set of facts in support of her failure to warn claims and then allege a conflicting set of facts in order to admit an expert to support those claims and to demand punitive damages flowing from those claims. "Such

clashing factual assertions, stated in the context of the same claim rather than as conceptually distinct alternative theories of liability, may be deemed judicial admissions." National Western Life Ins. Co. v. Merrill Lynch, Pierce, Fenner & Smith, Inc., 175 F. Supp. 2d 489, 492 (S.D.N.Y. 2000).

Although Plaintiff may not argue that she developed ONJ later than September 2003, there is a genuine issue of material fact as to whether Merck's duty to warn arose before then. Summary judgment is therefore inappropriate.

3. Aggravating ONJ as an Injury

The parties' arguments on Plaintiff's failure to warn claims raise an additional question: Can Boles maintain a failure to warn claim on the ground that her already existing ONJ was aggravated because she remained on Fosamax after Merck's duty to warn arose?

Merck contends that this position is not viable. Specifically, Merck argues that Plaintiff (1) has not provided any expert testimony that remaining on Fosamax aggravated her condition and (2) has not established that Merck's failure to warn proximately caused her continuing injuries. Plaintiff responds by pointing to the testimony of Dr. Alastair Goss, one of the Plaintiffs Steering Committee's ("PSC") general causation experts, who stated at his deposition that he would remove a patient from Fosamax if they had stage 1 ONJ.

Merck's first point is well taken: Plaintiff has offered no reliable evidence that remaining on Fosamax after she had already developed ONJ aggravated her condition. The testimony of Dr. Goss that she attempts to rely on reads as follows:

> Q. Now you reference that you will cease the prescription of the bisphosphonates as a – as a – in consult with the general practitioner or the treating practitioner. Why is that part of your protocol [for dealing with patients suffering from stage 1 ONJ]?
>
> A. The reason for that is that with bisphosphonate-associated ONJ almost certainly the bone turnover has been turned off, so that if you keep supplying the drug, then you're going to make them worse. So that the concept is that you – that you cease them taking the drug, so that you give the bone a chance to recover.

(Pl.'s Ex. 7 at 85:9-20.) This response constitutes the full extent of Dr. Goss's discussion of the benefits of discontinuing Fosamax for patients with ONJ. Nowhere is this opinion stated in his expert report or the reports of any the general causation experts designated by the PSC. In extensive Daubert briefings, the PSC has not sought to establish, under Rule 702, the reliability of an opinion that remaining on Fosamax after it has allegedly caused ONJ exacerbates the condition. Such an assertion also is inconsistent with Plaintiff's admission that, once she developed ONJ in 2003, it became "too late to save [her] jaw." (Pl.'s Mem. in Opp'n 20.) It is also undermined by her admission that the zone of dead bone has "remained stable"

since 2003, despite the fact that she stopped taking Fosamax in 2006.

Plaintiff has offered no admissible evidence demonstrating that Fosamax poses a risk to patients already suffering from ONJ. Therefore, Merck is granted summary judgment on Plaintiff's negligence and strict liability claims to the extent they are predicated on Merck's failure to warn Plaintiff about the risks of Fosamax after Plaintiff had already developed ONJ.

C. Causation

Merck argues that Plaintiff cannot establish causation for two reasons: (1) The testimony of Plaintiff's specific causation expert is inadmissible, and (2) there is no evidence that Plaintiff's prescribing doctor would have done anything differently had he known that Fosamax could cause ONJ.

1. Expert Testimony on Specific Causation

According to Merck, there is no scientific basis for Dr. Hellstein's opinion that Fosamax caused Plaintiff's ONJ.[10] In support of this claim, Merck highlights Dr. Hellstein's admission that Plaintiff's various symptoms were consistent with

[10] Plaintiff argues that, by not raising this argument in its Daubert motion, Merck waived its challenge to Dr. Hellstein's expert opinion on the specific cause of Plaintiff's ONJ. However, in its Daubert motion, Merck expressly challenged the admissibility of Dr. Hellstein's opinion, stating that it would rely on the arguments made in the instant motion. (Def.'s Mem. of Law in Supp. of Motion to Exclude Expert Testimony on Daubert Grounds 72.) The Court therefore does not consider Merck's challenge waived.

conditions that occur in the absence of bisphosphonate use. For example, Dr. Hellstein conceded that denture irritation could explain Plaintiff's August 2002 swelling and that a persistent infection could explain her symptoms in 2003. Merck particularly seizes on Dr. Hellstein's alleged inability to determine whether the cause of a given case of ONJ was Fosamax or an infection. Although Dr. Hellstein testified that there are "clues" that permit him to differentiate between the two causes, Merck notes that he has not published these findings, subjected them to peer review, or verified them through a scientifically sound study. Merck asserts that the only basis for Dr. Hellstein's opinion is that Boles took Fosamax and then developed the disorder. Merck maintains that such a post hoc, ergo propter hoc argument is insufficient to prove causation.

Dr. Hellstein reached his conclusion that Fosamax caused Bole's ONJ through the use of "differential diagnosis." "[D]ifferential diagnosis is a patient-specific process of elimination that medical practitioners use to identify the 'most likely' cause of a set of signs and symptoms from a list of possible causes." Ruggiero, 424 F.3d at 254 (internal quotation marks omitted). "[L]ike any process of elimination, it assumes that the final, suspected 'cause' remaining after this process of elimination must actually be capable of causing the injury." Id. (internal quotation marks omitted). Therefore, "[w]here an

expert employs differential diagnosis to 'rule out' other potential causes for the injury at issue, he must also 'rule in' the suspected cause, and do so using scientifically valid methodology." Id. (internal quotation marks omitted).

The Court has already ruled that Dr. Hellstein reliably opined, based on scientifically valid methodologies, that Fosamax can cause ONJ. See In re Fosamax Prods. Liab. Litig., No. 06-cv-09455-JFK, at 21, 35 (July 27, 2009). In other words, Dr. Hellstein has ruled in Fosamax as a possible cause of ONJ generally. Merck now questions whether Dr. Hellstein, in the specific case of Boles, has adequately ruled out other possible causes, such as denture irritation or an infection.

"While an expert need not rule out every potential cause in order to satisfy Daubert, the expert's testimony must at least address obvious alternative causes and provide a reasonable explanation for dismissing specific alternate factors identified by the defendant." Israel v. Springs Indus., No. 98 CV 5106, 2006 U.S. Dist. LEXIS 80863, at *20 (E.D.N.Y. Nov. 3, 2006); accord Cooper v. Smith & Nephew, Inc., 259 F.3d 194, 202 (4th Cir. 2001) ("A medical expert's opinion based upon differential diagnosis normally should not be excluded because the expert has failed to rule out every possible alternative cause of a plaintiff's illness."); Westberry v. Gislaved Gummi AB, 178 F.3d 257, 265 (4th Cir. 1999).

Dr. Hellstein has adequately addressed the obvious alternative causes of Plaintiff's ONJ. In particular, he reasonably explained that the long-term presence of exposed bone and the inefficacy of debridement and antibiotics allowed him to rule out certain possible alternative causes such as cancer, trauma, and osteomyelitis, a kind of bone infection. Given the thoroughness of Dr. Hellstein's differential diagnosis and the acceptance of that methodology's reliability, Dr. Hellstein's failure to publish his findings or otherwise subject them to peer review does not trouble the Court. See Kumho Tire Co. v. Carmichael, 526 U.S. 137, 150 (1999) (holding that the Rule 702 inquiry is "a flexible one," without a "definitive checklist or test," that must be "tied to the facts of a particular case" (internal quotation marks omitted)).

Dr. Hellstein's expert opinion is admissible and is sufficient to make specific causation a question of material fact.

2. Proximate Causation

Under Florida law, a plaintiff cannot maintain a failure to warn claim without proving that the failure proximately caused his or her injury. See Alvarez v. Gen. Wire Spring Co., No. 8:07-cv-1319, 2009 U.S. Dist. LEXIS 6878, at *23 (M.D. Fla. Feb. 1, 2009). "One method of negating proximate cause is for the defendant to demonstrate that even an adequate warning would not

have altered the particular plaintiff's course of conduct." Stanley Indus., Inc. v. W.M. Barr & Co., 784 F. Supp. 1570, 1574 (S.D. Fla. 1992). Since drug manufacturers have a duty to warn the prescribing physician rather than the patient, see Buckner v. Allergan Pharms., 400 So. 2d 820, 822 (Fla. Dist. Ct. App. 1981), it is the prescribing physician's course of conduct that is most relevant to proximate cause in the prescription drug context.

Merck argues that Plaintiff cannot meet its burden of establishing proximate cause. Specifically, Merck claims there is no evidence in the record that Plaintiff's prescribing physician, Dr. Mills, would have done anything differently had Merck warned him of Fosamax's risks. In response, Plaintiff offers Dr. Mills's June 2, 2009, declaration in which he states, among other things, that had he known about Fosamax's true benefits and risks, he might not have prescribed it to Boles. Merck counters with two arguments: (a) Dr. Mills's declaration is inadmissible, and (b) Merck's alleged failure to reveal that Fosamax would not benefit certain patients did not proximately cause Boles's injury.

a. Admissibility of Dr. Mills's Declaration

Merck's first argument requires the Court to determine, as a preliminary matter, whether Dr. Mills's declaration is in fact an expert opinion. The question of whether to consider treating

physicians as expert witnesses or fact witnesses is somewhat unsettled. See Badr v. Liberty Mut. Group, Inc., No. 3:06CV1208, 2007 U.S. Dist. LEXIS 73437, *10-12 (D. Conn. Sept. 27, 2007) (discussing the "split of authority" on the issue). Many courts classify treating physicians as fact witnesses if their testimony is confined to certain topics directly related to their treatment of the plaintiff. See Perkins v. Origin Medsystems Inc., 299 F. Supp. 2d 45, 56 (D. Conn. 2004) ("A treating physician can testify as a fact witness about the care and diagnosis rendered as part of a plaintiff's treatment." (citing Santoro v. Signature Constr., Inc., No. 00 Civ. 4595, 2002 U.S. Dist. LEXIS 17286, at *4 (S.D.N.Y. Sept. 16, 2002)); Turner v. Delta Air Lines, Inc., No. 06 CV 1010, 2008 U.S. Dist. LEXIS 5528, at *4 (E.D.N.Y. Jan. 25, 2008) ("[I]f the witness testifies only to the opinions formed in providing plaintiff medical care, such opinions are considered an explanation of treatment notes and the physician may properly be characterized as a fact witness."); Cruz v. Henry Modell & Co., No. CV 05-1450, 2008 U.S. Dist. LEXIS 25340, at *32-38 (E.D.N.Y. Mar. 31, 2008) (permitting treating psychologist to testify as a fact witness regarding the causes of his patient's psychological disorders).

Other courts find that treating physicians' testimony invariably draws upon their specialized knowledge, requiring

that they be qualified as experts. See Lamere v. N.Y. State Office for the Aging, 223 F.R.D. 85, 87-88 (N.D.N.Y. 2004) ("[W]e cannot completely limit a treating physician to solely factual testimony . . . [since she has] specialized knowledge and, in the scheme of her physician duties, provides opinions of various nature in the process of treating to her patient.").

Often, the determination is based on the specific facts of the case and the content of the proffered testimony itself. See Guarnieri v. Pa. Fed'n. Bhd. of Maintenance of Way Employees, 153 F. Supp. 2d 736, 745 (E.D. Pa. 2001) ("Given the complex physical and psychological injuries that [plaintiff] allegedly suffered, the Court determines that [plaintiff's treating physician] will not be permitted to testify as a lay witness."); Badr v. Liberty Mut. Group, Inc., No. 3:06CV1208, 2007 U.S. Dist. LEXIS 73437, at *11-12 (D. Conn. Sept. 27, 2007) (considering a treating physician to be a "hybrid" expert where he testified about his patient's "course of treatment, progress and prognosis, [and] possible origins of her mental or emotional condition").

To the extent Dr. Mills's declaration discusses what he would have done differently had he known about the alleged benefits and risks of Fosamax, the declaration constitutes an expert opinion. Portions of the declaration – specifically paragraphs 10 through 13, which Plaintiff cites in support of

her proximate causation argument – concern Dr. Mills's hypothetical course of treatment had he been aware of Fosamax's fracture efficacy and the risks posed by the suppression of bone turnover. This is not an explanation of how Dr. Mills actually did treat Boles or what opinions or diagnoses he actually formed – testimony that would put the treating physician in the role of fact witness. Rather it is a statement of hypothetical action that calls for Dr. Mills to process new information and ultimately form a new opinion. Dr. Mills could only form this new opinion – which was based on his understanding of the significance of fracture reduction efficacy and adverse event reports – by drawing on his specialized knowledge and experience as a physician. Therefore, the declaration constitutes an expert opinion.

The Court now considers (i) whether Plaintiff's failure to identify Dr. Mills as an expert should result in the exclusion of the declaration, (ii) whether Plaintiff improperly manufactured the expert opinion to defeat summary judgment, and (iii) whether there is a sound basis for Dr. Mills's new opinion.

i. Rule 37(c)(1) Preclusion

When a party fails to disclose the identity of an expert witness pursuant to Rule 26(a)(2)(A) of the Federal Rules of Civil Procedure, that witness may not be used to supply evidence

at trial or on a motion unless the failure was substantially justified or harmless. Fed. R. Civ. P. 37(c)(1). Before precluding evidence on these grounds, courts consider the following factors: "(1) the party's explanation for the failure to comply with the discovery order [or rule]; (2) the importance of the testimony of the precluded witness; (3) the prejudice suffered by the opposing party as a result of having to prepare to meet the new testimony; and (4) the possibility of a continuance." Softel, Inc. v. Dragon Med. & Sci. Communs., 118 F.3d 955, 961 (2d Cir. 1997).

On July 8, 2009, recognizing the importance of Dr. Mills's declaration to Plaintiff's case, the Court issued an order permitting Merck to redepose Dr. Mills to cure any prejudice caused by Plaintiff's failure to designate him as an expert. See Fanning v. Target Corp., No. 05 Civ. 12, 2006 U.S. Dist. LEXIS 4804, at *9-10 (S.D.N.Y. Feb. 6, 2006) (allowing defendant to depose two of plaintiff's experts after the close of discovery to cure the prejudice caused by plaintiff's failure to timely designate the witnesses as experts). Merck seized this opportunity and deposed Dr. Mills regarding his declaration on July 22, 2009. Having cured any prejudice to Merck, the Court finds that there is no need to resort to the extreme sanction of precluding this important evidence.

ii. Manufactured Declaration

Merck next argues that the timing and circumstances of Dr. Mills's declaration suggest it was improperly manufactured for the purpose of defeating summary judgment. In support, Merck makes the following claims: First, the declaration contradicts Dr. Mills's earlier deposition testimony (he was first deposed on June 18, 2008). Second, the declaration is unsupported in that, at his recent deposition, Dr. Mills could not recall the details of some of the events he described in the declaration, such as his meetings with Merck sales representatives. And third, Plaintiff's attorneys drafted the declaration and may not have provided Dr. Mills with some of the documents he referenced therein until after it was signed and filed.

The first part of Merck's argument implicates the "sham affidavit rule," which holds that a plaintiff cannot submit a declaration to defeat summary judgment that contradicts the declarant's prior deposition testimony. See Palazzo ex rel. Delmage v. Corio, 232 F.3d 38, 43 (2d Cir. 2000); Perma Research & Dev. Co. v. Singer Co., 410 F.2d 572, 578 (2d Cir. 1969). However, the rule "does not apply where the later sworn assertion addresses an issue that was not, or was not thoroughly or clearly, explored in the deposition." Palazzo, 232 F.3d at 43.

Dr. Mills's declaration is not a sham affidavit. It does not in fact contradict the deposition testimony that Merck highlights in its supplemental brief, such as those portions explaining how Dr. Mills learned about the efficacy of Fosamax. The alleged contradictions concern areas that were not fully or clearly explored at Dr. Mills's initial deposition. The Court finds that there are no discrepancies that would justify excluding Dr. Mills's declaration under the sham affidavit rule.

Merck's second and third arguments raise serious questions about the accuracy and credibility of the statements and opinions contained within Dr. Mills's declaration. Questions of this kind are for the jury and not the Court to resolve, however. See Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 255 (1986) ("Credibility determinations, the weighing of the evidence, and the drawing of legitimate inferences from the facts are jury functions, not those of a judge, whether he is ruling on a motion for summary judgment or for a directed verdict."). Dr. Mills twice affirmed under penalty of perjury that the declaration is true and correct – first, when he signed the declaration, and then again at his second deposition. For the purposes of summary judgment, the Court accepts these representations as true. See id. ("The evidence of the nonmovant is to be believed, and all justifiable inferences are to be drawn in his favor.").

Therefore, the Court declines to exclude Dr. Mills's declaration on the ground that it was manufactured to defeat summary judgment.

iii. Admissibility under Rules 702 and 703

Merck further contends that, even if not precluded by Plaintiff's discovery infractions or the sham affidavit rule, Dr. Mills's expert opinion is inadmissible under Rules 702 and 703 of the Federal Rules of Evidence. Specifically, Merck argues, "Mills is not qualified to render such an opinion; his opinion is based purely on a one-sided presentation of facts from counsel, and his declaration presents no scientific basis for that opinion." (Def.'s Reply Mem. 8 n.7.)

Merck's arguments assume that Dr. Mills is being offered as an expert on the causation of ONJ or the efficacy of Fosamax. In truth, Plaintiff merely offers Dr. Mills as an expert on general patient treatment, such as what factors should be considered and what precautions should be taken when prescribing medications. Dr. Mills does not have to explain why Fosamax lacks efficacy for certain patients in order to testify that a warning that it does lack efficacy would make him think twice before prescribing it. He also does not have to explain why Fosamax causes ONJ in order to testify that he would hesitate to prescribe the drug if its label warned that the suppression of bone turnover could lead to adverse event outcomes. Dr. Mills

is clearly qualified to offer expert opinions of this kind based on his forty years of experience as a board-certified physician and the thirty years he spent as Boles's doctor. See McCullock v. H.B. Fuller Co., 61 F.3d 1038, 1043-44 (2d Cir. 1995) (finding a doctor to be an expert based, in part, on his experience in the field and with a particular patient).

In sum, Dr. Mills's declaration is admissible as an expert opinion.

b. Failure to Reveal Efficacy and Proximate Cause

According to Merck, even if admissible, Dr. Mills's declaration does not establish proximate causation. As Merck reads it, the declaration merely states that Dr. Mills might not have prescribed Fosamax for Boles had he known its true fracture reduction efficacy. What it does not explicitly say, though, is whether Dr. Mills would have prescribed Fosamax had he known of the risk of ONJ – the injury for which Plaintiff seeks relief in this case. Merck argues that it does not matter what Dr. Mills would have done differently had he known the drug's true benefits; all that is relevant here is whether the failure to warn of the drug's risks proximately caused Plaintiff's injury.

Merck misreads Dr. Mills's declaration: it does in fact suggest that he would have acted differently had he known about the risk of ONJ. Dr. Mills states that he received no warning that the suppression of bone turnover "could have clinically

significant adverse event outcomes." (Pl.'s Ex. 14 ¶ 13.) As discussed in greater detail in the Court's Daubert ruling, suppression of bone turnover is considered a plausible explanation for how Fosamax may cause ONJ. See In re Fosamax Prods. Liab. Litig., No. 06-cv-09455-JFK, at 35 (July 27, 2009). Dr. Mills concluded that knowledge of these adverse event outcomes would have likely led him to change his plan of treatment. (Pl.'s Ex. 14 ¶ 13.) Drawing every inference in favor of Plaintiff, the Court finds that Dr. Mills's declaration raises a genuine issue of material fact as to whether he would have changed his course of conduct had Merck warned him that Fosamax could lead to adverse event outcomes such as ONJ.

Summary judgment on the issue of proximate causation is therefore inappropriate.

E. Fraudulent Misrepresentation and Concealment

To maintain a claim of fraudulent misrepresentation or concealment under Florida law, a plaintiff must establish the following elements:

> (1) a misrepresentation of material fact or suppression of the truth; (2) [a] knowledge of the representor of the misrepresentation, or [b] representations made by the representor without knowledge as to either truth or falsity, or [c] representations made under circumstances in which the representor ought to have known, if he did not know, of the falsity thereof; (3) an intention that the representor induce another to act on it; and (4) resulting injury to the party

> acting in justifiable reliance on the representation.

Pulte Home Corp. v. Ply Gem Indus., Inc., 804 F. Supp. 1471, 1483 (M.D. Fla. 1992) (citing Albertson v. Richardson-Merrell, Inc., 441 So. 2d 1146, 1149-50 (Fla. Dist. Ct. App. 1983)). Where a pharmaceutical company fraudulently misrepresents or conceals the risks of a drug to physicians, patients to whom those physicians subsequently prescribe the drug have a claim against the company. Albertson, 441 So. 2d at 1150. ("[A] fraud upon the physician [is] a fraud upon the patient." (citing Wechsler v. Hoffman-La Roche, Inc., 9 N.Y.S.2d 588 (Sup. Ct. 1950))); Stevens v. Danek Med., Inc., No. 95-14293-CIV, 1999 U.S. Dist. LEXIS 22397, at *16 (S.D. Fla. Apr. 16, 1999).

Merck argues that there is no evidence that it made a specific misrepresentation to Plaintiff or her doctor that they relied upon. This argument rests on Merck's assertion that it had no duty to warn of the risks of ONJ prior to Plaintiff's developing the condition. In its reply brief, Merck also makes the same proximate causation argument refuted above, namely, that Dr. Mills would not have done anything differently had he known about the risk of ONJ.

The Court has already considered and rejected these arguments. Dr. Parisian’s expert opinion creates a genuine issue of material fact as to whether Merck’s duty to warn

existed before September 2003, the time by which Plaintiff concedes she had developed ONJ. Dr. Mills's declaration creates a genuine issue of material fact as to whether he would have acted differently had he received an adequate warning. Merck's arguments are thus unavailing.

Summary judgment is inappropriate on this claim, except to the extent Plaintiff predicates the claim on her developing ONJ after September 2003 or on asserting that Fosamax aggravated her already existing ONJ.

C. Punitive Damages

Florida's statute governing punitive damages reads in relevant part,

> (2) A defendant may be held liable for punitive damages only if the trier of fact, based on clear and convincing evidence, finds that the defendant was personally guilty of intentional misconduct or gross negligence. As used in this section, the term:
>
> (a) "Intentional misconduct" means that the defendant had actual knowledge of the wrongfulness of the conduct and the high probability that injury or damage to the claimant would result and, despite that knowledge, intentionally pursued that course of conduct, resulting in injury or damage.
>
> (b) "Gross negligence" means that the defendant's conduct was so reckless or wanting in care that it constituted a conscious disregard or indifference to the life, safety, or rights of persons exposed to such conduct.

Fla. Stat. § 768.72.[11]

[11] Merck cites White Construction Co. v. Dupont, a Florida Supreme Court case, for the proposition that gross negligence,

In Florida, the "best-known" definition of clear and convincing evidence is evidence that is "credible, distinctly remembered, precise, and explicit." Lee County v. Sunbelt Equities, II, Ltd. P'ship, 619 So. 2d 996, 1006 (Fla. Dist. Ct. App. 1993) (internal quotation marks omitted) (citing Slomowitz v. Walker, 429 So. 2d 797, 800 (Fla. Dist. Ct. App. 1983)). In other words, "evidence which must be of such weight that it produces in the mind of the trier of fact a firm belief and conviction, without hesitancy, as to the truth of the allegation sought to be established." Id. (internal quotation marks omitted).

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in the punitive damages context, is equivalent to the level of culpability required to convict someone of criminal manslaughter. 455 So. 2d 1026 (Fla. 1984). This standard "all but eliminated punitive damage awards in products liability cases." Jeep Corp. v. Walker, 528 So. 2d 1203, 1205 (Fla. Dist. Ct. App. 1988). The White Construction line of cases predates the 1999 amendment to section 768.72 quoted above in the text, however. Some courts have concluded that the 1999 amendment superseded the earlier case law. See City of St. Petersburg v. Total Containment, Inc., No. 06-20953-civ., 2008 WL 5428179, *24-26 (S.D. Fla. Oct. 10, 2008); IBP, Inc. v. Hady Enters., Inc., 267 F. Supp. 2d 1148, 1170 (N.D. Fla. 2002) (disregarding cases "decided before the Florida legislature's amendment of Section 768.72"). But see Tiger Point Golf & Country Club v. Hipple, 977 So. 2d 608, 610-11 (Fla. Dist. Ct. App. 2007) (citing White Construction and other pre-1999 decisions). The Court finds that the statute, as amended in 1999, is clear enough on its face to be applied without turning to potentially superseded case law for interpretive assistance.

Ms. Boles argues that the record supports her claim for punitive damages under either the intentional misconduct or gross negligence standard. She points to the following evidence as proof: the adverse event reports of exostosis from the mid- to late-1990s, which Dr. Parisian believes Merck should have been aware of; the fact that, "even after publicly admitting to the [the risk of ONJ], Merck removed slides containing the number of ONJ cases from presentations it sent to ONJ task forces and has never released the full number (in the thousands) of ONJ reports in its database, not even to its own experts" (Pl.'s Mem. in Opp'n 20); and Merck's promotion of Fosamax for patients whom it would not actually benefit.

No jury could reasonably find by clear and convincing evidence that Merck's actions rose to the level of intentional misconduct. There is no evidence – let alone clear and convincing evidence – that Merck had "actual knowledge" of the "high probability" that Fosamax would cause Boles to develop ONJ. Fla. Stat. § 768.72(2)(a). The adverse event reports upon which Plaintiff relies so heavily do not discuss ONJ, but instead address patients with symptoms and conditions that could possibly, but not necessarily, indicate ONJ. While these reports are sufficient to create a question of material fact as to whether Merck should have known about the risk of ONJ, they

fall well short of being clear and convincing evidence that Merck had actual knowledge of this risk.

No jury could reasonably find by clear and convincing evidence that Merck's actions were so "reckless or wanting in care that it constituted a conscious disregard or indifference to the life, safety, or rights of persons" treated with Fosamax. Id. § 768.72(2)(b). Merck's failure to act upon a handful of reports of exostosis from the mid- to late-1990s, which may or may not have been ONJ, is insufficient to produce in the mind a firm belief or conviction that Merck was grossly negligent. The same is true of Plaintiff's allegation that Merck removed slides or omitted pertinent information from e-mails it sent to ONJ task forces. These e-mails were sent in 2006 and 2007 (Pl.'s Ex. 15 at 175:11-199:20), years after Plaintiff admits she developed ONJ. Given the timing of the e-mails relative to Plaintiff's injury, the Court finds that Plaintiff was not "exposed" to this conduct in such a way that would suggest a conscious disregard for her rights or safety. Fla. Stat. § 768.72(2)(b). Finally, Merck's marketing the drug to people whom it might not benefit is largely irrelevant to this issue.

Merck is granted summary judgment on the issue of punitive damages.

CONCLUSION

Merck's motion for summary judgment is granted in part and denied in part. The motion is granted on Plaintiff's negligence strict liability, and fraudulent misrepresentation and concealment claims to the extent these claims are predicated on (a) Plaintiff's developing ONJ later than September 2003 and (b) Fosamax's aggravating Plaintiff's already existing ONJ. The motion is also granted on Plaintiff's request for punitive damages. The motion is denied in all other respects.

SO ORDERED.

Dated: **New York, N.Y.**
August 5, 2009

JOHN F. KEENAN
United States District Judge